

In re Application of: Shih *et al*  
Serial No.: 09/431,519  
Filed: November 1, 1999

### REMARKS

The time for filing a response to the October 7, 2005 Office Action will expire on April 7, 2006. Applicants are filing this response on or before April 7, 2006 with a petition for a three month extension of time. Accordingly, it is respectfully submitted that this response is timely filed. If any additional fee is due, the Commissioner is hereby authorized to charge the same to Deposit Account No. 19-0365.

Claims 43-57 are pending in the application. Claims 43-57 stand rejected. Claims 21-42 were withdrawn by the Examiner. Applicants have added new claims 58-70. In response to the Examiner, applicants are filing the present amendment to address those concerns.

Support for previously presented claims 43-57 can be found in originally filed claims 1-20 and in the specification at page 7, lines 9-14. No new matter has been added with the filing of this amendment. Applicants have added new claims 58-70 and support their entry with the remarks below.

In view of the new claims and remarks below, applicants respectfully submit that the application is in condition for allowance. Accordingly, applicants request reconsideration of the application, withdrawal of the rejections of record, and issuance of Notice of Allowance.

#### **Rejections under 35 U.S.C. §112 First paragraph.**

The Examiner rejected Claims 1-8 and 13-20 under 35 U.S.C. §112, first paragraph for failing to comply with the written description requirement. Applicants respectfully traverse this rejection.

The Examiner stated that there is no support for zeranol ONLY but rather RALGRO™, which is zeranol formulated with lactose (see also specification, page 7, line 14-15).

In response to the rejection, applicants respectfully point out to the Examiner that on page 7, lines 9-14, the specification states that in "the immediate-release formulation, the anabolic agent **maybe used as is** or **optionally formulated** with minor amounts of other materials such as, for example, diluents. . . these materials include lactose as a diluent. . . " (EMPHASIS ADDED).

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Applicants have added new claims 58-70 to cover those embodiments of the invention that do contain optional diluent materials, such as lactose. Support for these claims can be found on page 7 as well as originally filed claims 1-20. Applicants have provided these claims in an effort to expedite the prosecution of this case as they also address the §112 first paragraph issue and provide an additional embodiment to the claimed invention as supported by the specification.

Therefore, applicants respectfully request the withdrawal of these rejections under §112, first paragraph.

**Previous Rejections under 35 U.S.C. §102 (b) and 35 U.S.C. §103.**

The Examiner stated that it would be obvious to provide an immediate acting growth stimulant while also provide a long term continual dosing form. The Examiner stated that the references of record do not show zeranol alone with a polymer zeranol form for controlled release. In fact, Nessel (US.3920806), cited for its description of formulation of lactose as a vehicle (col. 2, lines 35-37 of Table 1) describes a comparison of a lactose vehicle VERSUS a representative polymer controlled-release vehicle. Nessel in fact teaches away from the combination of an immediate release formulation in combination with a controlled release formulation. Applicants respectfully suggest that new claims 58-70 avoid the same prior art issue in that they are limited to an anabolic agent consisting of zeranol.

Therefore in light of these comments and previously submitted arguments regarding O'Callaghan , Stevens (US 5874098), Dick (GB 2167662) and Ivy (US 4670949) applicants respectfully submit that there are no potential issues regarding either ob

Applicants respectfully submit that in view of the above response, applicants have sufficiently addressed the Examiner's rejections and that the application, as amended, is in condition for allowance.

If any additional fees, other than any potential extension of time fees, are determined to be due by this paper, the Commissioner is hereby authorized to deduct such fees from **Account No. 19-0365**.

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If for any reason the Examiner believes that an interview would be helpful to resolve any remaining issues, he is invited to telephone the undersigned at the number listed below.

Respectfully submitted,



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